

REMARKS/ARGUMENTS

Reconsideration of the above-identified application is respectfully requested.

Claims 1, 3, and 5-15 and 17-23 remain under consideration. Claims 4, 16, 24-25 are previously cancelled/withdrawn.

In the Final Office Action dated January 4, 2006, the Examiner indicates that she has treated claim 3 as withdrawn because it fails to recite the compound swertiamarin.

Claims 1, 5-9 and 12 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims in co-pending applications SN 10/079416 and SN 10/948206.

In response to this provisional rejections, Applicants have decided to file a terminal disclaimer accompanying this submission to overcome the rejections.

Claim 1 is rejected under 35 U.S.C. § 112, second paragraph. Additionally, claims 1 and 6 remain rejected under 35 U.S.C. § 102(b) over Yamahara et al., Journal of Ethnopharmacology (Abstract) (hereinafter "Yamahara").

In response to these rejections, Applicants have amended claim 1 to incorporate the limitation of claim 8 into claim 1, and cancelled claim 6.

Claims 12-15 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

In response to the rejections, Applicants have cancelled claims 12-15.

Additionally, new claim 26 is added, which is the same claim as claim 10 except that claim 10, as amended previously, is now depending upon claim 5, which has been amended as an independent claim (claim 5 was a dependent claim of claim 1). Therefore, it is necessary to add

new claim 26 to provide the same limitation for the independent claim 1. No new matter has been introduced.

Applicants respectfully submit that the amendments have overcome the rejections for the reasons set forth below:

Double Patenting

Claims 1, 5-9 and 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims in co-pending applications SN 10/079416 and SN 10/948206.

In response, Applicants have decided to file a terminal disclaimer accompanying this submission to obviate the rejections.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 3, and 6-15 are rejected under 35 U.S.C. § 112, second paragraph, for issue of indefiniteness. The Examiner argues that claim 1, as previously amended, is still a compound claim, which does not match with claims 6-15, which appear to be drawn to a composition.

However, for different reasons, Applicants have now amended claim 5 as an independent “method” claim. Since claims 6-11 (Applicants have decided to cancel claims 12-15 for unrelated reasons) are now dependent claims of claim 5, they are no longer related to claim 1, so that whether claim 1 is a compound claim or a composition claim is no longer the cause for a rejection under 35 U.S.C. § 112, second paragraph.

Nevertheless, Applicants have decided to amend claim 1 as a pharmaceutical composition by incorporating the limitations in claims 6 and 8 into claim 1 for unrelated reasons. The amendment of claim 1, therefore, renders this rejection moot.

Claim rejections under 35 U.S.C. §102(b)

Claims 1 and 6 remain rejected under 35 U.S.C. §102(b) in view of Yamahara.

In response to the rejections, Applicants have incorporated the limitation of claim 8, to the currently amended claim 1, so that the pharmaceutical composition, as claimed in claim 1, contains (1) a cytochrome P450 3A (CYP3A) inhibitor, (2) a drug that undergoes a first-pass effect in a patient, and (3) at least one pharmaceutically acceptable excipient.

To anticipate a claim, each and every element of the claim must be taught, either expressly or inherently, in a single prior art reference. *See e.g., Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) (“a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”).

Yamahara never expressly or inherently teaches or suggests a drug that undergoes a first-pass effect in a patient, to be co-administered with CYP3A inhibitor. Thus, Applicants’ claimed invention is not anticipated by Yamahara.

Claim rejections under 35 U.S.C. §112 First Paragraph

Claims 12-15 are rejected under 35 U.S.C. §112, First Paragraph, as failing to comply with the written description requirement.

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In response to these rejections, Applicants have cancelled claims 12-15, so that the issues are moot.

Conclusion

In view of the foregoing, the objections and rejections have been overcome and the claims are in condition for allowance, early notice of which is requested. Should the application not be passed for issuance, the examiner is requested to contact the applicant's attorney to resolve the problem.

Respectfully submitted,

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